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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,836	10/03/2003	Manoussos Perros	PC10925B	1139
28940 7590 03/07/2006			EXAMINER	
	PHARMACEUTICA CE CENTER DRIVE	OWENS, AMELIA A		
SAN DIEGO			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/678,836	PERROS ET AL.				
		Examiner	Art Unit				
		Amelia A. Owens	1625				
	The MAILING DATE of this communication app		orrespondence address				
Period for	Reply						
WHICH - Extensi after SI - If NO pi - Failure Any rep	RTENED STATUTORY PERIOD FOR REPLY IEVER IS LONGER, FROM THE MAILING DA ons of time may be available under the provisions of 37 CFR 1.13 X (6) MONTHS from the mailing date of this communication. eriod for reply is specified above, the maximum statutory period w to reply within the set or extended period for reply will, by statute, sly received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1)⊠ F	Responsive to communication(s) filed on 10/17/2005.						
2a) <u></u> ⊤	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
•	- ' '						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositio	n of Claims						
4)× C	4)⊠ Claim(s) <u>41,42 and 46</u> is/are pending in the application.						
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) 🗌 C	5) Claim(s) is/are allowed.						
6)⊠ C	☑ Claim(s) <u>41,42 and 46</u> is/are rejected.						
	Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Applicatio	n Papers						
9)□ ⊤	ne specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority un	der 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. ☐ Certified copies of the priority documents have been received.							
Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s		<b>∧</b> □	(DTO 442)				
	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948)	4)  Interview Summary Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:							

Application/Control Number: 10/678,836 Page 2

Art Unit: 1625

## **DETAILED ACTION**

1. Claims 41,42,46 are pending.

2. Claim 45 has been canceled.

## Claim Rejections - 35 USC § 112

- 3. The rejection of claims 38-44 under 35 USC 112, 2<sup>nd</sup> paragraph has been dropped as the claims have been amended and/or canceled.
- 4. The rejection of claims 38-40,43,44 under 35 USC 112, 1<sup>st</sup> paragraph is dropped as the claims have been canceled.
- 5. Claims 41,42,46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the factors have been considered but only the most relevant will be discussed below.

The nature of the invention: The nature of the invention is the method of treating HIV infection in a mammal. See claims.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease).

There is no nexus between CCR5 and curing/preventing HIV. Chemokine CCR5 receptors are known to be associated with inflammatory diseases. At the time of the invention there was no umbrella drug known to cure/prevent HIV.

Art Unit: 1625

Guidance and working examples: Compounds according to the invention have been made. The specification @ page 29 lines 4-5 define treatment to include curative, palliative and prophylactic. Thus the claims are drawn to preventing or curing HIV infection. The claims are not enabled for this breadth of scope. Applicants have not shown the claimed compounds effective preventing or curing HCV infection. Applicants' assertions either that the compounds would be effective or that the compounds are effective are not enough. The abstract cited in the 5/3/05 response to the 112, 1<sup>st</sup> rejection using UK-427857 does not cure or prevent HIV.

The data in the specification is noted. CCR5 binding is known to be associated with inflammatory diseases. There is no nexus between CCR5 and treating HIV.

Since insufficient guidance and teaching have been provided by the specification, the skilled artisan, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amelia A. Owens
Primary Examiner
Art Unit 1625